

FDA Intends to Remove Unapproved Drugs from Market

FDA announced Wednesday that the agency intends to remove certain unapproved prescription medicines intended to relieve cough, cold, and allergy symptoms from the U.S. market.

These products have not been evaluated by FDA to assure that they are safe, effective, and of good quality. These products may therefore pose unnecessary risk to consumers, especially when there are other products available for treatment of cough, cold, and allergy symptoms, including FDA-approved prescription drugs or over-the-counter drugs that follow appropriate FDA standards.

FDA officials say they have numerous concerns about these products: some may have potentially risky combinations of ingredients, while others—marketed as “timed-release”—may release active ingredients too slowly, too quickly, or inconsistently. FDA has also received reports that some of the products have names that look or sound similar to other products—a problem that could contribute to medication errors.

In addition, FDA health experts are concerned that some of the products are inappropriately labeled for use by infants and young children. Many of the unapproved drug products covered by today’s announcement contain the same ingredients as the over-the-counter cough and cold products that were the subject of a 2008 FDA public health advisory.

That 2008 advisory said non-prescription cough and cold prod-



ucts should not be used for infants and children under 2 years of age because of serious and potentially life-threatening side effects. Many manufacturers voluntarily with-

drew products labeled for children under 2 years old, and some products were relabeled to state that they were not for use by children under 4 years old.

There are many other products—both prescription and over-the-counter—available for treatment of cough, cold, and allergy symptoms that meet FDA standards.

Safe and Effective Drugs

“Removing these unapproved products from the market will reduce potential risks to consumers from products that have never been evaluated by the FDA for safety, effectiveness, and quality,” says Deborah Autor, compliance director at FDA’s Center for Drug Evaluation and Research.

FDA says most manufacturers affected by today’s action must stop making the products within 90 days and stop shipping them within 180 days. (Some manufacturers may have to stop making and shipping their products immediately.) Autor says taking them off the market shouldn’t create problems for consumers because there are many other products—both prescription and over-the-counter—available for treatment of cough, cold, and allergy symptoms that meet FDA standards.

Some of the prescription medicines being removed have been marketed for many years. Over the past century, the laws outlining the requirements for drug approval have changed. First, drug regulation focused on adulteration and misbranding, but did not require that new drug products be approved prior to being marketed. Then, laws on drug regulation changed to include drug safety as a

requirement for approval.

Currently, the law requires that new drugs be shown to be safe, effective, of good manufacturing quality, and not misbranded prior to being approved by FDA for marketing in the United States. In part as a result of these changes in the law, many of the products that are the focus of this action have been marketed without being approved under the current legal requirements.

Approved Drugs Lists

If you are taking a prescription medicine for cough, cold, or allergy symptoms and you want to know if it is an approved drug, use one of the FDA resources listed below. (These resources do not include many over-the-counter drugs because many of these drugs do not require FDA approval to be legally marketed.)

- **Drugs@FDA** (contains most FDA-approved drug products): www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
If a product is not included here, the search results will say “Your search term did not return any results.”
- **The Orange Book List of Approved Drug Products:** www.accessdata.fda.gov/scripts/cder/ob/default.cfm
If a product is not FDA approved,

the search results will say, “No matching records found.”

- **The National Drug Code (NDC) Directory of prescription drugs and insulin products:** www.accessdata.fda.gov/scripts/cder/ndc/default.cfm

Search results include a column marked “Appl No.” FDA-approved products will have an associated NDA (new drug application) or ANDA (abbreviated new drug application) number in this column.

If you are taking one of the unapproved prescription medications that are affected by this FDA action, discuss alternatives with your health care provider. To dispose of your unused, unapproved prescription cold, cough, or allergy products, please see the following link: www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm

Find this and other Consumer Updates at www.fda.gov/ForConsumers/ConsumerUpdates

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